

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

IN RE SELENIOUS ACID LITIGATION	C.A. No. 2:24-cv-7791-BRM-CLW (consolidated)
AMERICAN REGENT, INC. v. SOMERSET THERAPEUTICS, LLC et al	C.A. No. 2:24-cv-07807-BRM-CLW
AMERICAN REGENT, INC. v. SOMERSET THERAPEUTICS, LLC et al	C.A. No. 2:24-cv-11124-BRM-CLW
AMERICAN REGENT, INC. v. SOMERSET THERAPEUTICS, LLC et al	C.A. No. 2:24-cv-11138-BRM-CLW

CONSENT JUDGMENT

American Regent, Inc. (“ARP”), and Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC (collectively, “SOMERSET”), parties in the above-captioned Actions, specifically in the Actions initiated by Plaintiff, ARI, against SOMERSET in Civil Action No. 2:24-07807-BRM-CLW, have resolved these litigations for good cause and valuable consideration recognized by ARI and SOMERSET. Now the parties, by their respective undersigned attorneys, hereby stipulate and consent to entry of judgment and an injunction in the Actions, as follows:

IT IS this ____ day of _____, 2025:

ORDERED, ADJUDGED AND DECREED as follows:

1. This District Court has jurisdiction over the subject matter of the above Actions and has personal jurisdiction over the parties.

2. As used in this Consent Judgment, (i) the term “SOMERSET Product(s)” shall mean the drug product(s) manufactured, sold, offered for sale or distributed pursuant to Abbreviated New Drug Application No. 218780 (including any supplements, or modifications, or

amendments thereto or replacements thereof) (“SOMERSET’s ANDA”); (ii) the term “Licensed ARI Patents” shall mean United States Patent No. 11,998,565 (“the ‘565 patent”) and United States Patent No. 12,150,957 (“the ‘957 patent”); and (iii) the term “Affiliate” shall mean any entity or person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with SOMERSET; for purposes of this definition, “control” means: (a) ownership, directly or through one or more intermediaries, of: (1) more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or (2) more than fifty percent (50%) of the equity interests in the case of any other type of legal entity or status as a general partner in any partnership; or (b) any other arrangement whereby an entity or person has the right to elect a majority of the Board of Directors or equivalent governing body of a corporation or other entity or the right to direct the management and policies of a corporation or other entity.

3. Unless otherwise specifically authorized by ARI or by 35 U.S.C. § 271(e)(1), SOMERSET, including any of its Affiliates, successors and assigns, is enjoined from infringing the Licensed ARI Patents, on its own part or through any Affiliate, by making, having made, using, selling, offering to sell, importing, or distributing of the SOMERSET Product(s) in the United States.

4. Compliance with this Consent Judgment may be enforced by ARI, its successors in interest, or assigns, as permitted by the terms of the Settlement Agreement.

5. This District Court retains jurisdiction to enforce or supervise performance under this Consent Judgment.

6. All claims, counterclaims, affirmative defenses and demands in these Actions are hereby dismissed without prejudice and without costs, disbursements or attorneys' fees to any party, except as otherwise agreed to by the parties.

7. Nothing herein shall preclude the U.S. Food & Drug Administration from granting final approval to SOMERSET's ANDA or shall preclude SOMERSET from filing, modifying, or maintaining with the FDA any Paragraph IV Certification for the SOMERSET Product(s) pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Brian R. Martinotti
United States District Judge

We hereby consent to the form and entry of this Order:

s/ Charles H. Chevalier

Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevailier@gibbonslaw.com

Christine A. Gaddis
GIBBONS P.C.
141 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801
cgaddis@gibbonslaw.com

OF COUNSEL:

Dennies Varughese, Pharm. D.
Uma Everet
Adam LaRock
Alex Alfano
Ryan Conkin

s/ James S. Richter

James S. Richter
MIDLIGE RICHTER, LLC
645 Martinsville Road
Basking Ridge, New Jersey 07920
(908) 626-0622

Of Counsel:

Kurt Mathas
Kevin Boyle
WINSTON & STRAWN LLP
35 W. Wacker Dr.
Chicago, Illinois 60601
Tel. (312) 558-5600
kmathas@winston.com
kboyle@winsoton.com

Claire Fundakowski
Lauren Rennecker
WINSTON & STRAWN LLP
1901 K Street, N.W.

Sterne, Kessler, Goldstein & Fox
P.L.L.C.

1101 K Street, NW, 10th Floor
Washington, DC 20005

(202) 371-2600

dvarughese@sternekessler.com

ueverett@sternekessler.com

alarock@sternekessler.com

aalfano@sternekessler.com

rconkin@sternekessler.com

*Attorneys for Plaintiff American
Regent, Inc.*

Washington, DC 20036

Tel. (202) 282-5000

cfundakowski@winston.com

lrennecker@winston.com

*Attorneys for Defendants Somerset Therapeutics,
LLC, Somerset Pharma, LLC, and Odin
Pharmaceuticals, LLC*